

REMARKS

Amendments

New claims 19 and 20 have been introduced to recite preferred embodiments of applicants' invention. No new matter has been introduced.

Claims Rejection 35 USC §103

In the Office Action mailed July 14, 2006, claims 1-4, 6-10 and 14-16 were rejected under 35 USC § 103(a) as being unpatentable over Patel et al (US 6,165,454) or Baravetto et al (US 6,174,522) or Fairley et al (US 2002/0192180). The assertion put forward by the Office in each case is that the "broad teachings" of the cited references would have suggested compositions having the same Zein solubility, fluorescein permeability and wet combing force properties as recited by the instant claims because the references suggest compositions containing the same components in the same proportions as the instant claims. Applicants respectfully disagree.

Because one could in principle randomly combine various optional or alternative materials disclosed in a publication so as to create specific combinations is no reason to do so.

Applying the standard expressed by the court in *In re Antonie* (195 USPQ 6 (Fed. Cir. 1977)) to the present invention, applicants submits that it would have been essential to the obviousness of carrying out a combinatorial experimental program to identify ingredients and levels to have recognized that certain specific surfactants selected from the plethora of recited ingredients in specific proportions might produce

exceptionally low eye irritation combined with excellent hair conditioning and to have had predictive tests to carry out such experiments. Otherwise, it would always be considered obvious to try varying every parameter of a system in order to optimize the effectiveness of the system in any property even if there is no evidence in the record that the prior art recognized that the particular parameters affected the results – a standard for obviousness under USC § 103(a) that was rejected by the court in *In re Antonie* (195 USPQ 6, 8, Fed. Cir 1977). Applicants submit the following arguments to demonstrate that the above elements essential for obviousness are absent in the publications cited by the Office.

Firstly, Patel et al, Baravetto et al and Fairley et al are all silent about the problem of eye irritation or its measurement. The words "eye", "ocular", "irritation", "zein", "fluorescein", "permeability", or "tear-free" are not mentioned in the reference. These references are also silent about any type of test or criteria for assessing mildness and eye irritation in general and zein solubility or fluorescein leakage assay in particular. Thus, the references would not have provided a person of ordinary skill in the art with either a reason or means of selecting from the various optional and alternative materials mentioned, those specific materials in the correct proportions so as to have produced compositions having low ocular irritation potential.

Secondly, none of the cited references disclose that combinations comprising an alkyl ethoxy sulfate surfactant having degree of ethoxylation of at least 3, a betaine surfactant and a hydroxysultaine surfactant would have had any unusual properties let alone the low ocular irritation potential that would arise only when the particular concentration ratios recited in claims 1 and 17 were met. This point is further supported by the following facts.

Not a single composition from among the 120 exemplary compositions disclosed in total by Patel et al (104), Baravetto et al and Fairley et al (1) recites a combination of an alkyl ethoxy sulfate having a degree of ethoxylation of at least 3, a hydroxysultaine and an alkyl betaine let alone at the proportions and ratios recited in applicants' claims. Applicants have shown (Example 5, page 45) that relatively small changes in composition of an alkylether sulfate/ betaine/ hydroxysultaine composition (e.g., changing from 3EO to 1EO alkyl ethoxy sulfate or changing from 7% to 10% alkyl ethoxy sulfate) makes the composition potentially irritant to eyes.

A previous declaration (dated April 15, 2006) from Cinda Carlson on file with the Office summarized Zein solubility experiments carried out with examples taken from Patel et al (4), Baravetto et al (2) and Fairley et al (the single example disclosed in the reference). The exemplary compositions employed were selected because they were believed by Ms Carlson based on her experience to be the mildest compositions among the examples disclosed. The results taken from Table 2 of the April 15, 2006 declaration are summarized below. They show that all the examples from the recited art have Zein solubility greater than 1% in contrast to the composition disclosed in the instant application (Example 5, Table 5 – page 45) where the Zein solubility is less than about 1%. Thus, all of the compositions would have significant eye irritation potential based on the Zein solubility test.

In response to the previously discussed declaration, the Office took the position that although the references do not teach the first property (Zein solubility) they nevertheless possess the second physical property (fluorescein leakage less than 10%). Applicants respectfully draw the Examiners attention to a second Declaration from Cinda Carlson filed with this amendment (dated September 28, 2006) which demonstrates that the Office's position is not consistent with the facts.

Zein Solubility of Examples Taken from Patel et al (US 6,165,454),
Baravetto et al (US 6,174,522) and Fairley et al (US 2002/0192180)

COMPOSITION	%ZEIN SOLUBILIZED ^a
Patel et al Ex 33	2.25±0.1
Patel et al Ex 44	3.27±0.09
Patel et al Ex 55	2.67±0.05
Patel et al Ex 73	1.63±0.08
Baravetto et al Ex VI	2.07±0.04
Baravetto et al Ex X	1.91±0.01
Fairley et al Ex 1	3.11±0.07
Example 5 of current application (10/764,114) (page 45 – table 5)	0.94

From Declaration of Cinda Carlson Dated April 17, 2006

In particular, the same compositions from the recited references that were tested previously in the Zein Solubility Assay were also tested in the Fluorescein Leakage Assay under the same conditions described in the specification (page 26-27). The results given in Table 2 of the September 28 Declaration are reproduced below. These results clearly demonstrated that all the compositions tested (which again are expected to be the mildest compositions among those disclosed in the cited art) all produce a fluorescein leakage of much greater than 10% after 24 hours and thus would be

classified as having significant eye irritation potential. In contrast, the fluorescein leakage produced by the compositions of the instant invention (e.g., examples 1A and 1B) induce a leakage of less than 10% and have low ocular irritation potential.

Permeability Based on Fluorescein Leakage Assay of Examples Taken from Patel et al, Baravetto et al and Fairley et al

COMPOSITION	% PERMEABILITY BASED ON FLUORESCIN LEAKAGE ^a		
	Initial	After 24 hrs	Combined Score
Compositions Disclosed in References Cited in Office Action 7/14/2006			
Patel et al Ex 33	13.0+/-2.2	64.2+/-10.6	77.2
Patel et al Ex 44	8.4+/- 0.7	49.1+/- 3.5	57.5
Patel et al Ex 55	11.1+/- 1.7	60.4+/- 9.9	71.5
Patel et al Ex 73	9.2+/- 1.6	47.5+/- 3.4	56.7
Baravetto et al Ex VI	11.9+/- 1.5	43.1+/- 4.5	55.0
Baravetto et al Ex X	12.2+/- 2.5	28.2+/- 8.4	40.4
Fairley et al Ex 1	12.2+/- 0.8	62.6+/- 16.9	74.8
Composition According to the present invention SN 10/764,114			
Ex 1A (page 38)	6.0+/- 0.9	1.0+/- 0.4	7
Ex 1B (page 38)	7.8+/- 0.9	1.0+/- 0.5	8.8
Controls			
Positive (Sodium Dodecyl Sulfate Solution)	9.2+/-1.0	36.2+/-14.7	45.4
Negative (HBSS buffer solution)	0.2+/-0	1.0+/-0.3	1.2

The Zein and Fluorescein assay results are quite consistent as was expected from the specification and taken together they demonstrate that the compositions disclosed in the references cited in the Office Actions would be unsuitable for a shampoo or body wash intended not to irritate eyes or be ultra mild to skin such as a conditioning shampoo for children.

In summary, Patel et al, Baravetto et al or Fairley et al alone or in combination would not have provided a person of ordinary skill in the art with any direction for selecting the specific materials at the specific levels and in the specific ratios so as to have achieved compositions having low ocular irritation potential. Ocular irritation is not even mentioned in the references, no tests are provided to quantify irritation potential and the mildest compositions disclosed in these publications have significant eye irritation potential measured on both tests.

In view of the above remarks, applicants respectfully request that the 103(a) rejection of their amended claims over Patel et al (US 6,165,454) or Baravetto et al (US 6,174,522) or Fairley et al (US 2002/0192180) be withdrawn.

Claims 11,12 and 17 were rejected as being unpatentable over Patel et al, Baravetto et al or Fairley et al in view of Booker et al (US 2003/0114323). Booker et al does not remedy the shortcomings of Patel et al, Baravetto et al or Fairley et al as prior art references. In particular, Booker et al does not provide any guidance that would have been suggested to one of ordinary skill in the art that combinations comprising an alkyl ethoxy sulfate surfactant having degree of ethoxylation of at least 3, a betaine surfactant and a hydroxysultaine surfactant would have had any unusual properties let

alone the low ocular irritation potential that would arise when they are combined at the specific ratios recited in claims 1 and 17.

Finally, Claim 17 recites a composition consisting essentially of 7 components in defined amounts subject to limitations on the ratios of 3 key components and recites further limitations on specific physical properties that ultimately is used to define the exact quantity of material within the ranges specified that will ensure both low eye irritation potential and high delivery of conditioning benefit. Applicants submit that there is no disclosure in any of the publications cited by the Office alone or in combination that would have suggested to the skilled artisan such a complex mixture with the recited limitations.

In light of the above remarks, applicants respectfully request that the 103(a) rejection of claims 11, 12 and 17 over Patel et al, Baravetto et al or Fairley et al in view of Booker et al (US 2003/0114323) be reconsidered and withdrawn and that the application be allowed to issue.

If a telephone conversation would be of assistance in advancing prosecution of the subject application, applicants' undersigned agent invites the Examiner to telephone him at the number provided.

Respectfully submitted,



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